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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,103	12/30/2005	Tore Duvold	3893-0219PUS2	6767
2292 7590 08/03/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
BADJO, BARBARA P				
ART UNIT		PAPER NUMBER		
1612				
NOTIFICATION DATE		DELIVERY MODE		
08/03/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/563,103

Applicant(s)

DUVOLD ET AL.

Examiner

Barbara P. Badio

Art Unit

1612

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20, 22, 25, 29, 30 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29, 30, 36 and 38 is/are allowed.
- 6) ☒ Claim(s) 1-20, 22, 25 and 37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/06)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 1-20, 22, 25, 29, 30 and 36-38 are pending in the present application.

Double Patenting

3. **The provisional rejection of claims 1-20, 22 and 25 on the ground of nonstatutory obviousness-type double patenting over claims of copending Application No. 12/087,743 is maintained.**

Applicant's statement that the rejection be withheld until either the present application or the copending '743 application grants as a patent is noted.

Claim Rejections - 35 USC § 112

4. **The rejections of claim 25 under 35 USC 112, first paragraph, scope of enablement are withdrawn.**
5. Claim 37 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claim recites "wherein the *in vivo* hydrolysable ester is selected....".

The instant specification lacks definition of the recited ester groups as "in vivo hydrolysable esters" and, thus, does not reasonable convey to the skilled artisan in the art that the inventor(s), at the time of the application was filed, had possession of the claimed invention.

6. The rejection of claims 20, 29, 30 and 36 under 35 USC 112, second paragraph is withdrawn.

7. The rejection of claims 1-19, 22 and 25 under 35 USC 112, second paragraph is maintained.

The claims recite "*in vivo* hydrolysable esters thereof". According to the instant specification, the expression "easily hydrolysable esters" is inclusive of "*in vivo* hydrolysable esters of the compounds of the invention". However, the instant specification does not set forth esters that are "*in vivo* hydrolysable". Therefore, the skilled artisan in the art at the time of the instant specification would be unable to determine the metes and bound of the claimed invention.

For this reason, the rejection of claims 1-19, 22 and 25 under 35 USC 112, second paragraph is maintained.

Claim Rejections - 35 USC § 103

8. The rejection of claims 1-7, 9, 10, 13-17, 19, 22 and 25 under 35 USC 103(a) over von Daehne (US 4,100,276 and 4,119,717) and Duvold (US 6,673,783) is maintained.

Applicant argues the claimed compounds show an unexpected and unobvious high activity against streptococci, whilst the activity against the three strains of staphylococci is maintained at the same level compared to the reference compounds (see Table A of the instant specification). According to applicant, the most the skilled person in the art would expect is that 24-C substituted derivatives would show antibacterial activity at the same level as compounds unsubstituted at the 24-C position. Applicant's argument was considered but not persuasive for the following reasons.

As noted in the previous Office Action, the substitution of hydrogen for methyl on a known compound is not patentable absent some unexpected or unobvious results. The data presented in Table A lacks comparison of the prior art compounds with the corresponding 24-methyl derivatives. The examiner also notes that all of the claimed compounds in Table A are 24-bromo derivatives of the cited prior art compounds and, thus, the data in Table A does not commensurate in scope with the instant claims.

Lastly, the examiner disagrees that the most the skilled artisan would expect is that 24-C substituted derivatives would show antibacterial activity at the same level as compounds unsubstituted at the 24-C position. Contrary to said assertion, the skilled artisan would expect difference in the potencies of the 24-methyl and that of the corresponding 24-unsubstituted derivative. What would be expected is that the 24-

methyl derivatives of the prior art compounds would have similar properties, i.e., they would be antibacterial agents.

For these reasons and those given in the previous Office Action, the rejection of claims 1-7, 9, 10, 13-17, 19, 22 and 25 under 35 USC 103(a) over von Daehne (US 4,100,276 and 4,119,717) and Duvold (US 6,673,783) is maintained.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Telephone Inquiry

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/
Primary Examiner, Art Unit 1612